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FDA APPROVES NEW LABORATORY TEST TO DETECT HUMAN INFECTIONS WITH AVIAN INFLUENZA A/H5 VIRUSES

Lab Test Developed by Centers for Disease Control and Prevention

HHS' Food and Drug Administration (FDA) today announced the approval of a new laboratory test to diagnose H5 strains of influenza in patients suspected to be infected with the virus. The test was developed by another HHS agency, the Centers for Disease Control and Prevention (CDC).

The product approved today is called the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set. The test provides preliminary results on suspected H5 influenza samples within four hours once a sample arrives at the lab and testing begins. Previous testing technology would require at least two to three days to render results. If the presence of the H5 strain is identified, then further testing is conducted to identify the specific H5 subtype (e.g., H5N1).

"This laboratory test is a major step forward in our ability to more quickly detect cases of H5 avian influenza and provides additional safeguards to protect public health," HHS Secretary Mike Leavitt said. "Thanks to the expeditious and collaborative efforts of CDC and FDA, the availability of this new test gives us one more tool to keep up with the ever changing nature of influenza viruses."

Since December 2003, more than 160 human cases of avian flu caused by the H5N1 strain of influenza have been reported in Thailand, China, Vietnam, Cambodia, Indonesia, Turkey and Iraq. More than half of the people infected with the H5N1 virus have died. Nearly all of these cases are believed to have been caused by exposure to infected poultry. The concern is that H5N1 will evolve into a virus capable of human-to-human transmission and lead to an influenza pandemic.

"Preparing for a possible flu pandemic is a top priority for our nation, and FDA acted quickly to evaluate and expedite CDC's request for approval of this test," Acting FDA Commissioner Dr. Andrew von Eschenbach said. "Using flexible regulatory authorities, FDA was able to prioritize this expedited approval based on the clear critical need without compromising the quality or integrity of the FDA review process."

A flu pandemic occurs when a new influenza virus emerges for which people have little or no immunity and for which there is no vaccine. In an influenza pandemic, the disease spreads easily from person to person in a sustained manner, causes serious illness, and can sweep across the country and around the world in very short time. It is difficult to predict when the next influenza pandemic will occur or how severe it will be.

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This test will be distributed to Laboratory Response Network (LRN)-designated laboratories to enhance early detection and surveillance activities as well as increase laboratory response capacity associated with a potential pandemic. Domestically the LRN is a system of about 140 labs in all 50 states. LRN labs have special experience and training in molecular testing methods, special bio-safety facilities and containment procedures as well as communication networks connected to public health programs across the country. The testing kits will be distributed by CDC beginning next week. CDC has also shared the test technology with the World Health Organization and its collaborating centers around the world.

"The use of this test by laboratories that are part of the LRN, in conjunction with other laboratory testing and clinical observations, may enable earlier detection of influenza cases caused by this specific virus and allow public health agencies to investigate sources of infection and more quickly respond with control and prevention activities," said CDC Director Dr. Julie Gerberding.

Information obtained from this test will be used to track cases of illness with this strain of virus. Testing for this virus is indicated when a patient has symptoms of severe respiratory illness and a risk of exposure (e.g., direct contact with sick, dead or infected poultry in a country with outbreaks of influenza H5N1 among poultry).

CDC recommends that testing for influenza A/H5 (Asian lineage) influenza should be considered on a case-by-case basis in consultation with local or state health departments. If a clinician suspects a patient may be infected with an avian influenza virus, they should contact their state or local health department. CDC's full recommendations are available at *http://www.cdc.gov/flu/avian/*.

For information on pandemic influenza, state summits and preparedness activities go to *http://www.pandemicflu.gov*.

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